

APR - 8 1998



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

#23

Todd M. Crissey
Patent Department
WARNER-LAMBERT COMPANY
2800 Plymouth Road
Ann Arbor, MI 48105

Re: Patent Term Extension
Application for
U.S. Patent No. 4,260,769

Dear Mr. Crissey:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,260,769 for a period of one-year. An appropriate notice thereof will be published in the Official Gazette.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

A handwritten signature in cursive script, appearing to read "Karin Tyson", written over a horizontal line.

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: CEREBYX® (fosphenutol sodium)
FDA Docket No.: 96E-0442

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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

In re	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,260,769	:	INTERIM EXTENSION

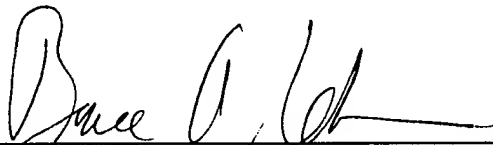
Warner-Lambert Company, agent of Merck & Co., Inc., the owner of record in the Patent and Trademark Office (PTO) of U.S. Patent No. 4,260,769, filed an application for patent term extension under 35 U.S.C. § 156 on August 30, 1996. The original term of the patent is due to expire on April 7, 1998. The patent claims the active ingredient fosphenytoin sodium in the human drug product "CEREBYX®" which was approved by the Food and Drug Administration for commercial marketing or use on August 5, 1996. An extension of 1,826 days is requested.

The initial PTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. However, in accordance with the limitation of 35 U.S.C. § 156(g)(6)(B), applicant appears entitled to an extension of five years. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,260,769 is granted for a period of one year from the original expiration date of the patent.

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Date



Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks